PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200201191 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00569	International filing date *(day/month/year)* 01.09.2003	Priority date *(day/month/year)* 02.09.2002
International Patent Classification (IPC) or both national classification and IPC A61M39/08		
Applicant UNOMEDICAL A/S ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 18 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.04.2004	19.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Lager, J Telephone No. +49 89 2399-2957

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00569

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-7 received on 05.07.2004 with letter of 29.06.2004

Claims, Numbers

1, 3-22 received on 05.07.2004 with letter of 29.06.2004

Drawings, Sheets

1/6-6/6 received on 05.07.2004 with letter of 29.06.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 2

   ☒ the drawings, sheets: 1/7-7/7

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,3-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1,3-22
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1,3-22
	No:	Claims	

2. Citations and explanations

   see separate sheet

Section V.

1. The assessment to novelty and inventive step below has been done on the assumption that the following amendments were done:

   Lines 10 and 25 of claim 1: replacement of "can" with "is adapted to";
   Line 6 of claim 12 at page 10: replacement of "can" with "is adapted to"; and
   Line 7 of claim 12 at page 11: replacement of "can" with "is adapted to".

1.1 Moreover, the applicant has indicated that claim 2 should be deleted. Claim 2 has therefore been left out in the assessment below.

2. The closest prior art is represented by document US-A-5 522 803 (=D1) which discloses a device according to the preamble of claim 1 and a medicament supply device according to the preamble of claim 12 although the tubing has not been disclosed as folded but being suitable to be folded.

2.1 The subject-matter of claims 1 and 12 differs from the teaching of D1 in that two holders, a first and a second, are defined which are arranged such that the tubing may be folded in parallel courses between the holders and that the first holder is adapted to be displaced along the tubing by movement of the tubing as defined in claims 1 and 12.

2.2 None of the available prior art suggests an arrangement as defined in any of claims 1 and 12 for the purpose of keeping tubing folded in a controlled manner. Document US-A-4 406 042 (=D2) discloses a similar arrangement as defined in the preambles of claims 1 and 12 and discloses further the usage of a clip to hold the tubing. D2 is however silent about a two holder arrangement.

The present definitions of claims 1 and 12 leads to easy adjustment for a user, in particular, when carried on the body preventing to tubing from coming into interference with the user and the surroundings.

2.3 Claims 1 and 12 therefore fulfil the requirements of Article 33(2)-(3) PCT.

3. Claims 3-11 define preferred embodiments of the device of claim 1 and claims 13-

22 define preferred embodiments of the medicament supply device of claim 12.

4. Claims 1, 3-22 do therefore fulfil the requirements of Article 33(2)-(4) PCT.

A device for subcutaneous administration of a medicament to a patient

The present invention relates to a device for subcutaneous administration of a medicament to a patient, comprising a cannula housing with an interior chamber, a cannula connected to said cannula housing and being in flow communication with the interior chamber, and a flexible tubing having a first end and a second end, wherein the tubing is, at the first end, coupled to the cannula housing such that the tubing is in flow communication with the interior chamber, and wherein, at its second end, the tubing carries a source coupling by which the tubing can be coupled to a source for said medicament; and wherein, between its first and its second end, the tubing is folded for forming a controlled configuration of the tubing with essentially parallel courses of tubing.

US patent No. 5,522,803, being now as a reference deemed to constitute a part of the present text, shows in Figures 1 and 2 a cannula housing to be adhered to the skin of the patient so as to enable continuous administration of a drug to the patient via a plastics needle introduced into the skin of the patient. At its one end a tubing features a coupling that is releasably secured to the cannula housing, whereby the tubing can be released from the cannula housing, eg when the patient is in the bath. At its other end the tubing features a a source coupling by which the tubing can be coupled to a source, such as a pump, thereby enabling the drug to be fed to the cannula housing through the tubing.

In some situations, eg when the patient is asleep it is necessary to have a relatively long distance between the cannula housing and the source of the drug to enable the source of drug to sit on a table next to the patient. Thus there is a need for a comparatively long tubing, eg a tubing having a length of about 1.1 m. Conversely, a short tubing is typically desired when the patient is up and about, ie when the source of drug is carried by the patient, eg in a

pocket in his clothes. To overcome this problem, it is an option to change tubing as day turns into night. This, however, may lead to waste of the usually very expensive medicament located in the long tubing.

It is previously been attempted to solve this problem by providing the source of drug with a winder mechanism for the tubing, see international patent application No. WO 96/35472. The winder mechanism described therein, however, cannot be manufactured at low costs and there is a risk of the winder mechanism getting stuck.

US-A-4 406 042 discloses a tubing clips where variation of the distance between the ends of the tubing is by changing the size of a tubing loop that projects from the clips.

It is the object of the present invention to provide a device for subcutaneous administration of a drug to a patient that can be be manufactured at low costs and that enables variations in the distance between the source of drug and the cannula housing.

This is accomplished in that, the device comprises a first and a second holder and in order to secure the tubing in said configuration, it is received in guides in a first holder device arranged between the first and the second end of the tubing and in guides in a second holder device arranged at the first or second end of the tubing or between the first and the second end of the tubing with parallel courses running between the holder devices; and that the first holder device can be displaced along the tubing in a direction towards the second holder device by movement of the tubing along said guides in the first holder device. Hereby it is possible to vary the effective distance between the cannula housing and the source of drug between approximately the length of the tubing and a distance determined by the number of folds on the tubing and the position of the holder device; and to adequately control the

courses of tubing and adequately support the tubing in the area around the folds. The second holder device may be an integral part of the cannula housing or the source coupling, or it may be configured in the same manner as the first holder device and may be arranged on the tubing as a separate component that is capable of being displaced along the tubing.

In the latter case, the effective distance between the cannula housing and the source of drug can be increased by manually displacing the holder devices towards each other along the tubing, ie along the respective courses of tubing, and then sort out the requisite length of tubing. Depending on the frictional resistance between the tubing and the holder device, said effective distance may alternatively be increased by merely applying a pull in the two ends of the tubing. The distance can subsequently be reduced by manually pulling the holder devices away from each other.

It is preferred that at least the first holder device is provided with guides for the tubing, preferably in the form of bores, ie closed channels, and these guides can be rectilinear or they can be curved and hence receive the fold(s) of the tubing and provide a certain protection of the tubing in these areas. Particular advantages from the point of view of mounting can be accomplished by configuring the one or both of the holder devices as a two-piece housing, thereby facilitating the mounting of the holder devices on the tubing.

In the present context, the term "parallel courses of tubing" is intended to designate one or two lengths of the tubing that has/have – apart from the folding area – courses that are mutually entirely parallel or converge towards each other within an angle interval of a very few degrees, eg 1-5°, so as to allow the courses of tubing to extend relatively close to each other irrespective of the position of the holder device along the tubing. Also, the

term "folded" is intended to designate a state in which the tubing continues to be able to convey medicament from the one end of the tubing to the other.

The invention also relates to a medicament supply device as recited in claim 12 that is suitable for being mounted on an existing system for subcutaneous administration of a medicament.

The invention will now be explained in further detail with reference to the drawing.

Figure 1 is a schematic view of a number of the elements necessary for subcutaneous administration of a medicament to a patient;

Figure 2 schematically shows a sectional view of an alternative embodiment of the invention, wherein the cannula housing and source coupling are omitted;

Figures 3a, 3b and 3c show a variant of the embodiment of Figure 2, wherein the cannula housing and source coupling are omitted.

Figures 4, 5a and 5b are alternative embodiments, wherein the second holder device is configured as an integral part of the coupling to the cannula housing; and

Figure 6 shows an embodiment in which the second holder device is configured as an integral part of the source coupling.

Figure 1 shows a part of a flexible tubing 4 having a first end 4' and a second end 4''. At its first end 4' the tubing 4 is provided with a coupling 3 configured for being, in a releasable manner, able to be secured to a cannula housing 1. The cannula housing 1 has an interior chamber that communicates with the

tubing 4 and with a cannula 2 that protrudes from the cannula housing 1 which is preferably flexible and of plastics and intended for being introduced through the surface of the skin of a patient by means of a not shown insertion needle. The interior chamber is not shown, but its configuration may like the one shown in US patent No. 5,522,803.

A source coupling 5 secured to the second end 4" of the tubing 4 makes it possible to releasably couple the tubing to a source for a drug. The term 'source' in this context is intended to designate a receptacle for the drug, a pump preferably being introduced between the receptacle and the coupling that, said pump supplying the drug to the patient via the tubing 4 in a predetermined dosage. The source coupling 5 is configured for being able to co-operate with a complementary coupling on said drug receptacle or on a tubing connected to the receptacle or pump. Preferably the tubing 4 is made of a plastics material and has such properties that, to a wide extent, the tubing 4 is able to prevent a local occlusion of the flow of the drug if the tubing 4 is folded sharply.

Figure 2 shows an embodiment of the invention, wherein two holder devices 10, 20 are used for providing a desire controlled configuration with three courses, 14, 24, 34 of tubing that extend between the holder devices 10, 20. Alternatively, it is certainly an option to configure the holder devices 10, 20 to form five courses of tubing.

The holder devices 10, 20 are shown in Figure 2 in a schematic sectional view and each of the holder devices 10, 20 comprises an internal semicircular guide 11 and an internal rectilinear guide 12, respectively. The semi-circular guide 11 serves to receive the fold 9, 9' of the tubing, while the rectilinear guide 12 conveys the tubing 4 into the area between the two holder devices 10, 20. The width of the guides 11, 12 are adapted to the diameter of the tubing 4, such that the tubing 4 is able to slide in the guides

11, 12 with a desired minimum friction. In order to increase the distance between the cannula housing and the source coupling, a pull is merely exerted in the tubing 4 at its ends 4', 4'', whereby the length of the individual courses of tubing is reduced, while simultaneously the holder devices 10, 20 move towards each other. Conversely, to increase the length of the courses 14, 24, 34 of tubings and thus to move the ends 4', 4'' of the tubing 4 towards each other, a pull is merely exerted in the holder devices 10, 20 in a direction away from each other. In both situations the holder devices are displaced along the tubing 4, the tubing 4 sliding in the guides 11, 12.

Figure 3a shows a variant of embodiment shown in Figure 2, wherein the holder devices 10, 20 are split, the two parts 10', 10'' being preferably articulated to each other and configured for being moved from an open state shown in Figure 3b to a closed state shown in Figure 3c, and to be secured in the latter state via a lock 15, such as a snap lock. Hereby the holder devices 10, 20 can be mounted in an existing system of the kind shown in Figure 1. In this embodiment, the holder devices 10, 20 comprise three rectilinear guides 11, 12, 13 for the tubing 4.

A further embodiment is shown in Figure 4, wherein the first holder device 10 is configured as described above with reference to Figure 2, but wherein the second holder device 20 is arranged at the first end 4' of the tubing 4 and is configured as an integral part of the cannula housing 1, said cannula housing 1 comprising an outer guide 11 for the fold 9 of the tubing 4. The guide 11 is preferably configured as a notch into which the tubing can be urged and that secures the tubing to the cannula housing 1. Like in the above-referenced embodiments, the guide 11 must be dimensioned such that the tubing 4 is able to slide in the notch when the first holder device 10 is pulled to the right in Figure 4 to increase the length of the courses 14, 24, 34 of the tubings.

Figure 5a and 5b show alternative embodiments, wherein the second holder device 20 is arranged at the first end 4' of the tubing 4 and is configured as an integral part of the coupling 3, whereby the tubing 4 is connected to the cannula housing 1. Thus, the coupling 3 secures, firstly, the end 4' of the tubing and, secondly, it also comprises two guides in the form of bores 11, 12 that secure the tubing in the region at the fold 9. The first holder device 10 can be configured like the holder device 10 shown in Figure 3c. An increase in the distance between the cannula housing 1 and the source coupling is accomplished merely by a pull in the tubing 4 at its ends 4', 4", whereby the length of the individual courses of tubing is reduced while simultaneously the first holder device 10 moves towards the second holder device 20. Conversely, an increase in the length of the courses 14, 24, 34 of the tubings, and hence movement of the ends 4', 4" of the tubing towards each other, is accomplished merely by a pull in the holder devices 10, 20 in a direction away from each other. In both situations the tubing 4 is displaced in the guides of the two holder devices 10, 20.

Finally Figure 6 shows an embodiment that, in principle, corresponds to the one shown in Figure 5a, but wherein the second holder device is configured as an integral part of the source coupling 5. The first holder device 10 can optionally be configured such that it can be locked releasably to the second holder device 20 and be separated there from, when the distance between the courses of tubing is to be increased as is shown at the bottom of Figure 6.

Claims

1. A device for subcutaneous supply of a medicament to a patient, comprising:

- a cannula housing (1) with an interior chamber;
- a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber;
- a flexible tubing (4) having a first end (4') and a second end (4''), wherein the tubing (4) is, at its first end (4') coupled to the cannula housing (1), such that the tubing (4) is caused to be in flow communication with the interior chamber; and wherein the tubing (4) carries a source coupling (5), at its second end (4''), by which the tubing (4) can be coupled to a source for said medicament;
- wherein the tubing (4) is, between the first and the second end (4', 4'') folded (9, 9') for forming a configuration with essentially parallel courses (14, 24, 34) of said tubing;

characterised in

- the device comprises a first and a second holder device (10,20);
- that in order for the tubing (4) to be secured in said configuration, it is received in guides (11, 12, 13) in said first holder device (10) arranged between the first and the second end (4', 4'') of the tubing (4) and in guides (11, 12, 13) in said second holder device (20) arranged at the first or second end (4', 4'') of the tubing (4) or between the first and second ends (4', 4'') of the tubing, with said parallel courses (14, 24, 34) running between said first holder device (10) and said second holder device (20), and
- that the first holder device (10) can be displaced along the tubing (4) in a direction towards the second holder device (20) by movement of the tubing (4) along said guides (11, 12, 13) in the first holder device (10).

2. A device according to the preceding claim, **characterised in** that the first holder device (10) is configured as a housing with at least two bores that form said guides (11,12, 13).

3. A device according to claim 2, **characterised in**
- that the second holder device (20) is arranged between the first and second ends (4', 4") of the tubing; and
- that the second holder device (20) can be displaced along the tubing (4) in a direction towards the first holder device (10).

4. A device according to the preceding claim, **characterised in** that the second holder device (20) is configured as a housing with at least two bores that form said guides (11, 12, 13).

5. A device according to any one of the preceding claims 1 or 2, **characterised in** that the second holder device (20) is constituted by the cannula housing (1) or by a coupling (3) by which the tubing (4) is connected to the cannula housing (1).

6. A device according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the cannula housing (1).

7. A device according to any one of the preceding claims 1 or 2, **characterised in** that the second holder device (20) is constituted by the source coupling (5).

8. A device according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the source coupling (5).

9. A device according to any one of the preceding claims, **characterised in** that the tubing (4) is bent for forming at least three essentially parallel courses (14, 24, 34) of tubing.

10. A device according to any one of the preceding claims, **characterised in** that the first holder device (10) and/or the second holder device (20) comprises two housing parts (10', 10'') configured for being movable between a first position in which there is access to said guides (11, 12, 13) for introduction into the guides (11, 12, 13) of the tubing (4) transversally to the longitudinal expanse of the guides (11, 12, 13), and a second position, in which the tubing (4) is fixated against movement out of the guides (11, 12, 13) transversally to the longitudinal expanse of the guides.

11. A device according to any one of the preceding claims, **characterised in** that the guides (11, 12, 13) are configured for optionally being blocked, whereby removal of the tubing (4) by withdrawal of the tubing (4) transversally to the longitudinal direction of the tubing is prevented.

12. A medicament supply device including a flexible tubing for supplying a medicament from a first end (4') thereof with a cannula housing coupling (3) for connecting said device to a cannula housing (1) that has an interior chamber and a cannula (2) connected to said cannula housing (1) in flow communication with the interior chamber, to a second end (4'') thereof having a source coupling (5), whereby the tubing (4) can be coupled to a source of said medicament, wherein said tubing (4) is, between the first and the second end (4', 4''), folded (9, 9') for forming a configuration with essentially parallel courses (14, 24, 34) of said tubing,

characterised in

- the device includes a first and a second holder device (10,20);
- that in order for the tubing (4) to be secured in said configuration, it is received in guides (11, 12, 13) in said first holder device (10) arranged

between the first and the second end (4', 4'') of the tubing (4) and in guides (11, 12, 13) in said second holder device (20) arranged at the first or second end (4', 4'') of the tubing (4) or between the first and second ends (4', 4'') of the tubing, with said parallel courses (14, 24, 34) running between said first holder device (10) and said second holder device (20), and

- that the first holder device (10) can be displaced along the tubing (4) in a direction towards the second holder device (20) by movement of the tubing (4) along said guides (11, 12, 13) in the first holder device (10).

13. A device according to the preceding claim, **characterised in** that the first holder device (10) is configured as a housing with at least two bores that form said guides (11, 12, 13).

14. A device according to claim 13, **characterised in**
- that the second holder device (20) is arranged between the first and second ends (4', 4'') of the tubing (4); and
- that the second holder device (20) can be displaced along the tubing (4) in a direction towards the first holder device (10).

15. A device according to the preceding claim, **characterised in** that the second holder device (20) is configured as a housing with at least two bores that form said guides (11, 12, 13).

16. A device according to any one of the preceding claims 12 or 13, **characterised in** the second holder device (20) is constituted by the cannula housing coupling (3).

17. A device according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the cannula housing coupling (3).

18. A device according to any one of the preceding claims 12 or 3, **characterised in** that the second holder device (20) is constituted by the source coupling (5).

19. A device according to the preceding claim, **characterised in** that the tubing (4) is received in guides (11) that extend interiorly of the source coupling (5).

20. A device according to any one of the preceding claims 12- 19, **characterised in** that the tubing (4) is folded for forming at least three essentially parallel courses (14, 24, 34) of tubing.

21. A device according to any one of preceding claims 12-20, **characterised in** hat the first holder device (10) and/or the second holder device (20) comprises two housing parts (10', 10") configured for being movable between a first position in which there is access to said guides (11, 12, 13) for introduction into the guides (11, 12, 13) of the tubing (4) transversally to the longitudinal expanse of the guides (11, 12, 13); and a second position in which the tubing (4) is fixated against movement out of the guides (11, 12, 13) transversally to the longitudinal expanse of the guides.

22. A device according to any one of the preceding claims 12-21, **characterised in** that the guides (11, 12, 13) are configured for optionally being blocked, whereby removal of the tubing by withdrawal of the tubing (4) transversally to the longitudinal direction of the tubing is prevented.

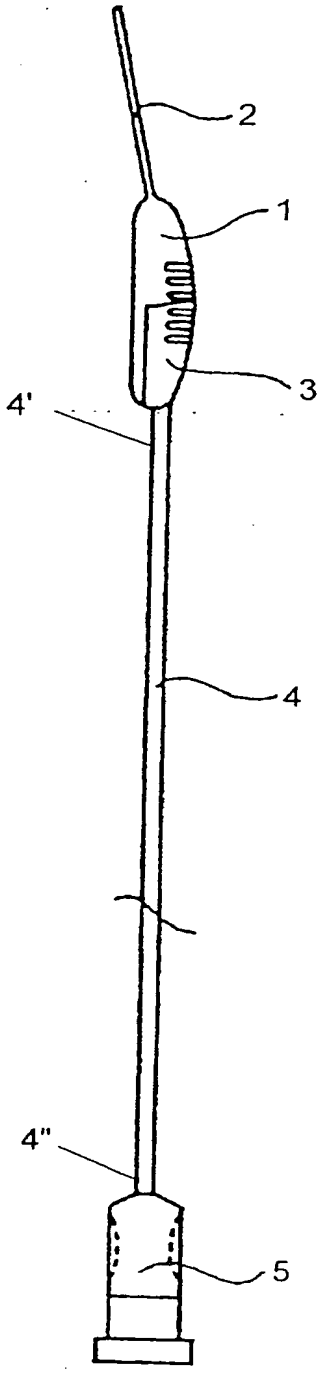

Fig. 1

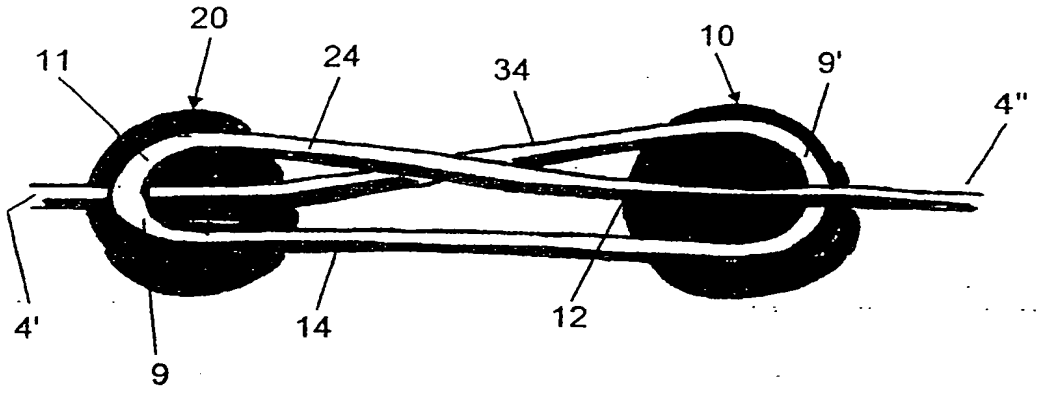

Fig. 2

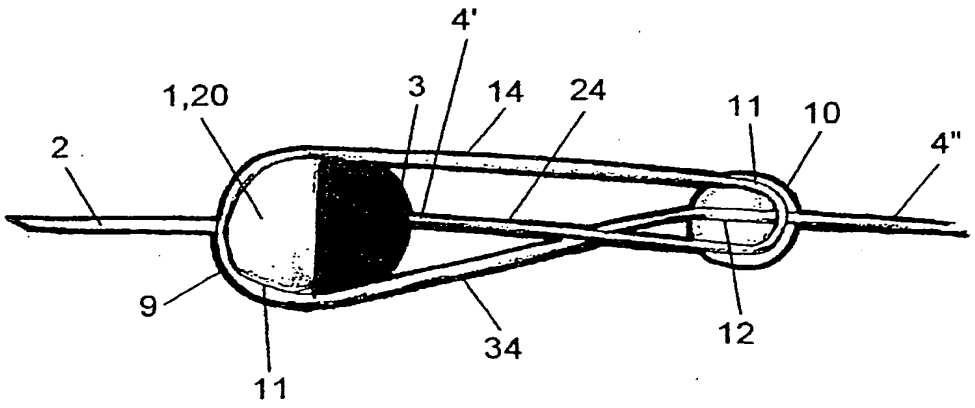

Fig. 4

Fig. 3a

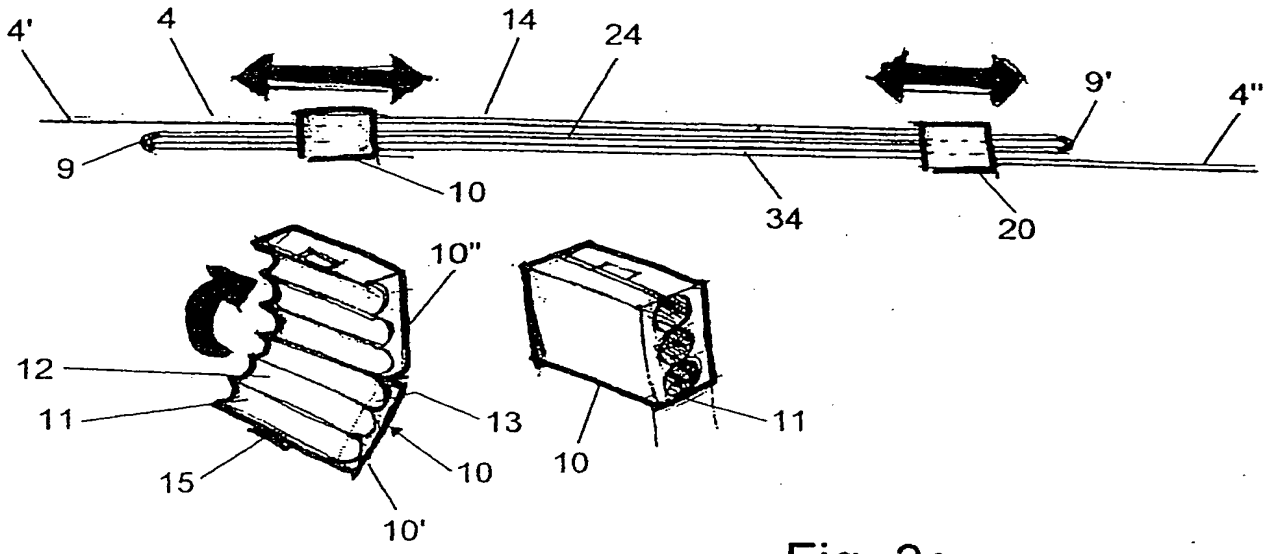

Fig. 3b

Fig. 3c

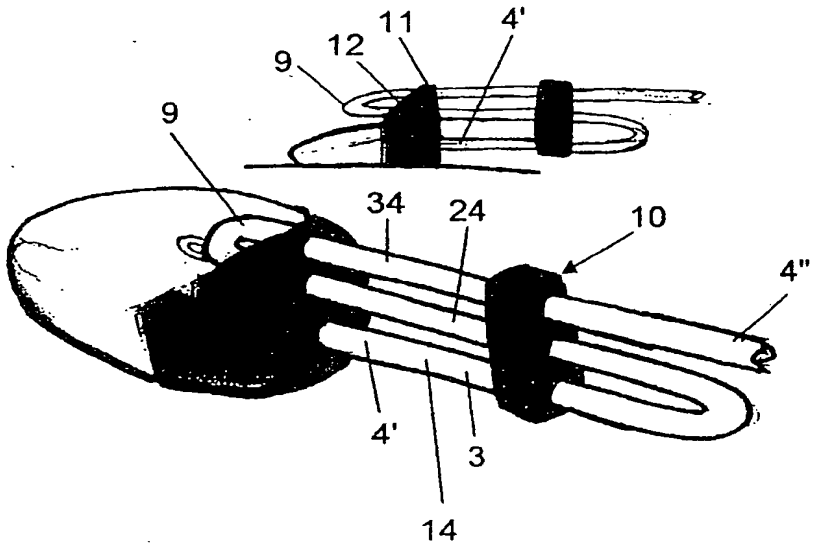

Fig. 5a

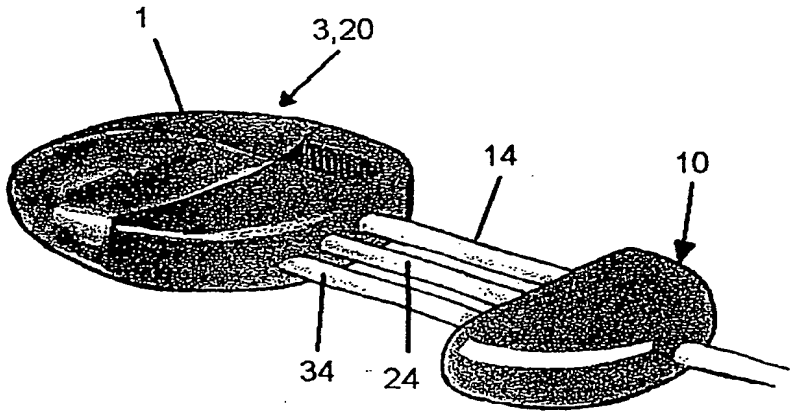

Fig. 5b

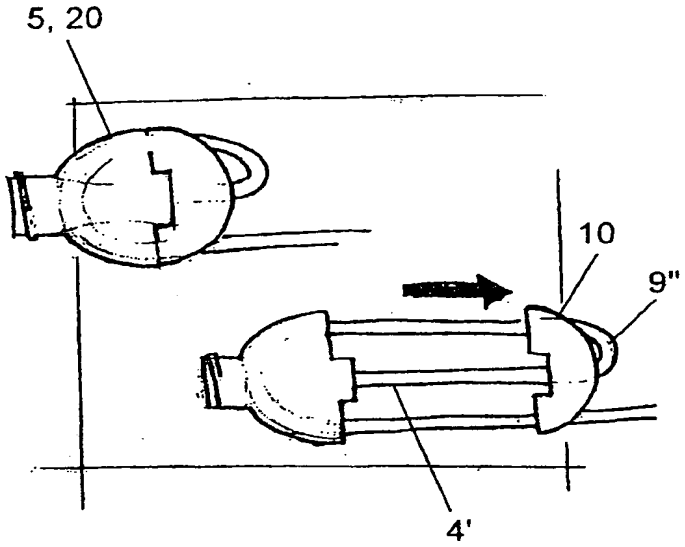

Fig. 6

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